

## PHARMACEUTICAL LABELING, ADVERTISING and PROMOTIONS POST-MASTER'S CERTIFICATE

*Focusing on the Federal and Global Regulations Governing Pharmaceutical  
Labeling, Advertising, and Promotions*

### BACKGROUND

Temple University's School of Pharmacy continues to be the leader in providing world renowned graduate-level courses in Regulatory Affairs and Quality Assurance. As the program launches new programs, it recognizes that many graduates with the MS in RAQA wish to continue taking courses to keep current with industry issues and meet regulatory requirements for training. The *Post-Master's Certificate in Pharmaceutical Labeling, Advertising and Promotions* allows RAQA graduates to pursue additional coursework and receive formal recognition for their work. The certificate is also open to professionals with other master's or doctoral degrees.

In the pharmaceutical industry, *labeling* refers to more than a prescription label or a cardboard container enclosing prescription or over-the-counter (OTC) products: *labeling* also refers to the *Prescribing Information* (or PI), which is a detailed and complicated product reference sheet, often folded in multiple accordion pleats and included with prescription or OTC products.

In the U.S., every PI is governed by the U.S. Code of Federal Regulations, Title 21, part 200, which stipulate that every aspect of the product be delineated in writing: a description of the drug dosage form and its physical properties; a listing of active ingredients and excipients; the molecular structure of each compound; the pharmacokinetics and toxicology of the drug; the intended patient population; potential side effects and safety concerns; unique storage requirements, and so forth.

The PI must accompany any print ads about prescription drugs that appear in journals and magazines. Attached to each advertisement, the PI must be uniquely coded, since the company is required to keep accurate records of where the ad appeared.

Federal regulations also govern how prescription products can be advertised. Each year pharmaceutical companies spend more than \$30 billion on direct-to-consumer (DTC) TV ads, which have made many products household names, from *Cymbalta* to *Humira*, from *Nexium* to *Lyricea*. The complexity of creating these ad campaigns, while complying with federal regulations, continues to be a challenging task that combines industry knowledge, regulatory expertise and marketing. Advertising companies alone cannot create the ads; regulatory professionals must be included.

In addition to DTC TV advertising, websites about pharmaceutical products have grown exponentially, particularly those that focus exclusively on one product, serving as a sort

of "patient reference page." In some cases, innovator companies even sell products DTC from websites.

Often different countries have unique regulatory requirements for labeling and advertising. Some require labels to display the price of a product the day it was granted approval by the governing regulatory authority. Or, product cartons must be designed to clearly display that pricing. As the types and global reach of product advertising continue to expand, thereby crossing the boundaries of regulatory authorities and patient populations, the need for more global regulatory oversight is increasing.

The *Post Master's Certificate in Pharmaceutical Labeling, Advertising, and Promotions* enables students to sharpen their knowledge of this industry niche without committing to the entire master's degree. This certificate provides the tools and information to understand the key domestic and global regulations that affect labeling, advertising, and promotions for pharmaceuticals and related products.

For more than 50-years, the School of Pharmacy of Temple University has provided outstanding graduate-level course work in Regulatory Affairs and Quality Assurance. The School was the original institution of higher learning in the world to create a master's program in the Regulatory Affairs (RA) and Quality Assurance (QA) disciplines and continues to offer the most comprehensive curriculum of its kind.

Temple's program specifically examines RA and QA issues facing the pharmaceutical and related industries by integrating pharmaceutical law and regulation, pharmaceutical technology, and quality assurance practices. Instructors are FDA and industry veterans with years of expertise in their specialties, sharing their vast knowledge with students through intimate classroom discussions and hands-on workshops.

Candidates must formally apply for the *Post-Master's Certificate in Pharmaceutical Labeling, Advertising, and Promotions* before registering for any courses. To receive the certificate, candidates must complete the required courses and application procedures. Students who completed master's degrees or higher from accredited U.S. institutions of higher learning with extensive pharmaceutical industry experience may also petition the School to pursue the *Post-Master's Certificate in Pharmaceutical Labeling, Advertising, and Promotions*, but they are required to complete *Food and Drug Law* (5592) before proceeding with any elective courses.

Temple's RAQA graduate program is based in Fort Washington, PA. Courses can also be videoconferenced to corporate sites. Classes are conveniently scheduled on evenings and weekends for working professionals. Over 80 courses are offered online in real time. This certificate may be completed online.

## LEARNING OBJECTIVES

Upon completion of the *Post Master's Certificate in Pharmaceutical Labeling, Advertising, and Promotions* students will be able to:

- Understand U.S./global regulatory and industry requirements for creating, updating, or maintaining product labeling;
- Explain the nature of the pharmaceutical marketplace and the roles of Congress, the courts, and the FDA in labeling, advertising, and promotional efforts;
- Evaluate specific advertising and promotion communications for regulatory compliance;
- Identify the latest trends and issues posed by Internet advertisements and product websites.

## ACADEMIC REQUIREMENTS

To earn the certificate, four (for Temple University RAQA graduates) or five courses (for students with other non-Temple advanced degrees) must be successfully completed within a four-year period with an overall B (3.0) average:

- **Food and Drug Law (5592)**
- **Requirements for Product Labeling and Advertising (5533)**
- **Global Labeling Regulation: Principles and Practices (5532)**
- **Regulation of Advertising and Promotions (5611)**
- One elective from the following (if the required courses have been taken in fulfillment of the MS):
  - **Drug Development (5459)**
  - **Advanced Topics in Labeling Development (5535)**
  - **Regulation of Non-Prescription Healthcare Products (5507)**
  - **Regulation of Dietary Supplements, Botanicals, and Nutraceuticals (5594)**

Students should take *Food and Drug Law* before pursuing other courses in the certificate, if they have not already done so. It is suggested that *Requirements in Product Labeling and Advertising* be completed next. The remaining courses may be taken in any order.

## APPLICATION PROCESS

### Temple University Students

Once you receive your MS from Temple, the University closes your academic file. If you wish to pursue the *Post Master's Certificate in Pharmaceutical Labeling, Advertising, and Promotions*, you must formally apply, so we can open your file to register you. The application is available on the **Certificates** link of the RAQA homepage. You will be required to take four courses relating to Labeling, Advertising, and Promotions to complete the Post Master's Certificate.

Please mail the application to:

Temple University School of Pharmacy  
Regulatory Affairs and Quality Assurance Graduate Program  
425 Commerce Drive, Suite 175  
Fort Washington, PA 19034

### Students with Advanced Science Degrees from Other Schools

To apply for the *Post-Master's Certificate in Labeling, Advertising, and Promotions*, you must meet the following criteria:

- 1) You must have received an advanced degree (master's level or higher) from an accredited institution of higher learning and must have worked in the pharmaceutical industry for a minimum of three years.
- 2) Please write a letter to the Assistant Dean (Temple University School of Pharmacy, RAQA Graduate Program, 425 Commerce Drive, Suite 175, Fort Washington, PA 19034), indicating which courses you wish to pursue and explaining your experience in the pharmaceutical industry. Include the Application for the *Post-Master's Certificate in Pharmaceutical Labeling, Advertising, and Promotions*, a copy of your resume, and copies of transcripts from all undergraduate and graduate programs you have attended. Formal permission to pursue the *Post-Master's Certificate in Pharmaceutical Labeling, Advertising, and Promotions* must be received from the Assistant Dean before commencing any courses in the program.
- 3) Students with advanced degrees from other schools will be required to take four Temple University RAQA courses to receive the *Post-Master's Certificate in Pharmaceutical Labeling, Advertising, and Promotions*. If the candidate subsequently decides to apply for the MS in Regulatory Affairs and Quality Assurance within five years, the credits earned in the *Post-Master's Certificate in Pharmaceutical Labeling, Advertising, and Promotions* will count towards the master's degree, provided a grade of B (3.0) or higher is earned in each course and the student is accepted into the MS program.

### TO RECEIVE THE CERTIFICATE

After you have finished the required courses, fill out the **Notice of Completion** (available on the RAQA website) and forward it to the RAQA Office by fax (267.468.8565), email (qarareg@temple.edu), or hard copy.

The RAQA Office issues certificates in early February, June, and September. In order to receive your certificate in one of those months, you must notify the RAQA Office **at least one month in advance**. Otherwise you will have to wait until the next time they are processed. The certificate must be completed within four years. Transfer credits are not accepted towards the Advanced Certificate.

## DESCRIPTION OF COURSES

### Required Courses

#### **5592. Food and Drug Law (3 credits)**

This course studies the governance of intra- and interstate commerce in foods, drugs, cosmetics, and medical devices and the effects of the Federal Food, Drug and Cosmetic Act upon research, manufacture, marketing, and distribution of drugs.

#### **5533. Requirements for Product Labeling and Advertising (3 credits)**

*Prerequisite: Food and Drug Law (5592) or permission of the instructor.*

This course examines strategies for creating drug labeling during new product development, for updating existing product labeling, and for creating “harmonized” core data sheets for products marketed globally. Students gain insight and awareness of current trends in advertising and promotional regulation.

#### **5611. Advanced Topics: Regulation of Advertising and Promotions (3 credits)**

This course reviews the regulatory and legal fundamentals of advertising FDA-regulated products, including prescription pharmaceuticals, OTCs, and biologicals. Discussions will include how these regulations differ from those applicable to restricted medical devices and food products.

#### **5532. Global Labeling Regulation: Principles and Practices (3 credits)**

*Suggested prerequisite: Drug Development (5459)*

This course provides a detailed analysis of corporate labeling practices in the United States and European Union (EU). It compares and contrasts FDA regulations with more recent EU and International Congress on Harmonization (ICH) regulations, including the impact on corporate labeling documents. A significant portion of the course will be devoted to new guidelines from FDA and the pharmacovigilance guidelines for the EU market and ICH.

### Elective Courses

#### **Drug Development (5459)**

This course studies the drug development process from discovery through FDA marketing approval. It reviews the process of development and the interrelationships linking the various disciplines, introducing students to regulations governing the process, including the interactions with FDA, ICH, and other regulatory agencies.

*This course is required for the MS in RAQA, the Drug Development Certificate, the Certificate in Clinical Trial Management, the Certificate in Biosimilars and Generic Drugs, and the Basic Pharmaceutical Development Certificate.*

*Not open to students who have taken RAQA 459. Advanced Topics in Labeling Development (5535)*

#### **Advanced Topics in Labeling Development (5535)**

*Prerequisite: Requirements for Product Labeling and Advertising (5533) or permission of the instructor.*

This course reviews the regulatory and legal fundamentals of labeling FDA-regulated products, specifically, prescription pharmaceuticals, emphasizing the direct application of the regulations to actual practice. It analyzes case studies and current practices, providing an overview of legal, regulatory, and marketing concepts affecting labeling. It discusses the application of current knowledge and explores new trends in the legal and regulatory framework surrounding the development and implementation of drug labeling. As a class project, students are assigned to drug development teams (Regulatory Affairs, Marketing and Clinical) and provided with the known data of their compounds. Teams determine what information is needed to complete the draft labeling for NDA submission, and develop a final label; they hold mock negotiations (internal and with the Agency) and propose changes to labeling in response to post-marketing surveillance.

*Not open to students who have taken RAQA 535*

### **Regulation of Non-Prescription Healthcare Products (5507)**

*Prerequisite: Food and Drug Law (5592)*

This course examines non-prescription healthcare products in the U.S., including their legal status (both past and present). Starting with discussions of how non-prescription healthcare products are classified, the course will focus on the Food and Drug Administration's OTC Monograph system and the OTC Monograph User Fee (OMUFA). Students will learn how non-prescription labeling evolved (including discussions on Drug Facts Labeling) and examine cases where prescription products were switched to OTC, including the impact of FDA's NSURE Initiative, a draft guidance that will facilitate Rx-to-OTC switches. A brief overview of Non-Prescription classifications outside the U.S. will also be included.

### **Regulation of Dietary Supplements and Functional Foods (5594)**

Functional foods and dietary supplements have been a fast-growing segment of the food market for the last half a decade owing to the aging demographics and scientific research demonstrating their effect on health. Regulation and judicial decisions have been influential for dietary supplement companies in producing and marketing their products. An understanding of how these regulation work and what influence they have on dietary supplement regulatory policy is critical. This course will provide information on the history of the regulation in the US and an in-depth look at the current regulatory outlook for these products in the US and in other select countries/regions.

*Not open to students who have taken RAQA 594.*

## **QUESTIONS AND ANSWERS**

### **Where is the RAQA Program Offered?**

The RAQA program is based at Temple University Fort Washington in suburban Montgomery County, PA. For directions, visit our website:

[http://www.temple.edu/pharmacy\\_QARA/map.htm](http://www.temple.edu/pharmacy_QARA/map.htm)

Courses can be videoconferenced directly to corporate sites. Over 70-courses are available online in real time.

This certificate may be completed entirely online.

### **When can I start the certificate?**

Courses in the RAQA program are offered during the fall, spring, and summer semesters every year. You may start the certificate program at your convenience.

### **What course sequence is recommended?**

We recommend starting this certificate with *Food and Drug Law* (5592), which is a prerequisite for *Requirements for Product Labeling and Advertising* (5533). Unless courses have prerequisites, you may take the remaining courses in any sequence.

The RAQA program offers over 80 different courses, which are rotated over a 2 to 3-year period. Courses are not necessarily offered every semester. We urge students to take courses when they are scheduled or to write to the RAQA Office if they wish to see a course scheduled in a particular semester.

### **How do I obtain a current class schedule?**

Please see the Schedule link of the RAQA homepage:

[www.temple.edu/pharmacy\\_QARA](http://www.temple.edu/pharmacy_QARA)

### **How do I register for classes?**

You must be formally admitted to the *Post-Master's Certificate in Labeling, Advertising, and Promotions* before registering for any courses.

- If you received your MS from Temple, download the registration form from the RAQA homepage: [http://www.temple.edu/pharmacy\\_QARA/forms.htm](http://www.temple.edu/pharmacy_QARA/forms.htm)  
You do not need to submit a state residency form, unless you have moved from one state to another.
- If you have not registered for Temple University RAQA courses before, download the Registration and State Residency forms from the RAQA homepage: [http://www.temple.edu/pharmacy\\_QARA/forms.htm](http://www.temple.edu/pharmacy_QARA/forms.htm)  
Both are required the first time you register. Fax, mail, and e-mail registrations do not guarantee your spot in a class, since sections do fill quickly. You will receive an email confirmation once you are registered and an electronic tuition bill through your Temple email account.

### **Do I need to take the GREs to complete the Certificate?**

No. GRE or other advanced test scores are not required for the certificate or the MS in RAQA.

### **Can I transfer any credits from another graduate institution towards the *Post-Master's Certificate in Labeling, Advertising, and Promotions*?**

Sorry, but credits for courses taken at other institutions are not accepted. All courses must be from Temple University's RAQA program. If you have taken identical or very similar courses at another institution, you may request to take an alternate course in its place.

**Will the certificate automatically be awarded when I complete the required courses?**

No. You must notify the RAQA Office that you have finished the certificate by submitting the **Notice of Completion** by the stated deadlines. The form is available on the RAQA website, under Certificates.

**How much time do I have to complete the *Post-Master's Certificate in Labeling, Advertising, and Promotions*?**

You should complete the *Post-Master's Certificate in Labeling, Advertising, and Promotions* within four years. When you have finished your courses, you must submit the **Notice of Completion** to the RAQA Office.

**Will new electives be added to the certificate programs?**

Yes, the RAQA program continues to expand its curriculum. For a listing of new courses, please consult the RAQA website.

**For additional information:**

**Temple University School of Pharmacy  
Regulatory Affairs and Quality Assurance Graduate Program**

425 Commerce Drive, Suite 175  
Fort Washington, PA 19034

**Voice: 267.468.8560**

**Fax: 267.468.8565**

**E-mail: [QARA@temple.edu](mailto:QARA@temple.edu)  
[www.temple.edu/pharmacy\\_QARA](http://www.temple.edu/pharmacy_QARA)**